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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANE K. FISHER and RAGHUNATH V. LALGUDI

Appeal 2008-0769
Application 09/394,745
Technology Center 1600

Decided: August 14, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 8-10 and 12-27, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

PROCEDURAL HISTORY

This is the second appeal of the subject matter of this Application. On November 22, 2005 a Decision was entered in the first appeal (Appeal No. 2005-1340) affirming the rejections of the claimed subject matter under 35 U.S.C. § 101 and the enablement provision of 35 U.S.C. § 112, first paragraph as lacking patentable utility (Decision 2). While a written description rejection was presented for our review in the first appeal, “[h]aving disposed of all claims on appeal [as lacking a patentable utility], we d[id] not reach the merits of the written description rejection” (Decision 3).

INTRODUCTION

The claims on appeal are directed to a microarray. Claim 14 is illustrative:

14. A microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO:

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SEQ ID NO: 6671, SEQ ID NO: 6674, SEQ ID NO: 6680, SEQ ID NO: 6685, SEQ ID NO: 6686, SEQ ID NO: 6688, SEQ ID NO: 6691, SEQ ID NO: 6692, SEQ ID NO: 6696, SEQ ID NO: 6697, SEQ ID NO: 6702, SEQ ID NO: 6704, SEQ ID NO: 6711, SEQ ID NO: 6716, SEQ ID NO: 6724, SEQ ID NO: 6726, SEQ ID NO: 6728, SEQ ID NO: 6739, SEQ ID NO: 6742, SEQ ID NO: 6744, SEQ ID NO: 6747, SEQ ID NO: 6764, SEQ ID NO: 6766, SEQ ID NO: 6770, SEQ ID NO: 6772, SEQ ID NO: 6773, SEQ ID NO: 6778, SEQ ID NO: 6781, SEQ ID NO: 6782, SEQ ID NO: 6790, SEQ ID NO: 6792, SEQ ID NO: 6841, SEQ ID NO: 6870, SEQ ID NO: 6871, SEQ ID NO: 6886, SEQ ID NO: 6894, SEQ ID NO: 6904, SEQ ID NO: 6906, SEQ ID NO: 6923, SEQ ID NO: 6931, SEQ ID NO: 6934, SEQ ID NO: 6938, SEQ ID NO: 6939, SEQ ID NO: 6949, SEQ ID NO: 6953, SEQ ID NO: 6961, SEQ ID NO: 6965, SEQ ID NO: 6978, SEQ ID NO: 6991, SEQ ID NO: 7000, SEQ ID NO: 7002, SEQ ID NO: 7036, SEQ ID NO: 7050, SEQ ID NO: 7053, SEQ ID NO: 7062, SEQ ID NO: 7070, SEQ ID NO: 7078, SEQ ID NO: 7083, SEQ ID NO: 7096, SEQ ID NO: 7100, SEQ ID NO: 7106, SEQ ID NO: 7107, SEQ ID NO: 7134, SEQ ID NO: 7144, SEQ ID NO: 7161, SEQ ID NO: 7164, SEQ ID NO: 7178, SEQ ID NO: 7206, SEQ ID NO: 7220, SEQ ID NO: 7221, SEQ ID NO: 7224, SEQ ID NO: 7228, SEQ ID NO: 7229, SEQ ID NO: 7241, SEQ ID NO: 7246, SEQ ID NO: 7248, SEQ ID NO: 7249, SEQ ID NO: 7254, SEQ ID NO: 7261, SEQ ID NO: 7267, SEQ ID NO: 7277, SEQ ID NO: 7332, SEQ ID NO: 7338, SEQ ID NO: 7351, SEQ ID NO: 7357, SEQ ID NO: 7369, SEQ ID NO: 7378, SEQ ID NO: 7380, SEQ ID NO: 7384, SEQ ID NO: 7386, SEQ ID NO: 7395, SEQ ID NO: 7438, SEQ ID NO: 7444, SEQ ID NO: 7447, SEQ ID NO: 7461, SEQ ID NO: 7463, SEQ ID NO: 7465, SEQ ID NO: 7468, SEQ ID NO: 7478, SEQ ID NO: 7490, SEQ ID NO: 7491, SEQ ID NO: 7492, SEQ ID NO: 7509, SEQ ID NO: 7514, SEQ ID NO: 7536, SEQ ID NO: 7559, SEQ ID NO: 7563, SEQ ID NO: 7565, SEQ ID NO: 7572, SEQ ID NO: 7576, SEQ ID NO: 7590, SEQ ID NO: 7592, SEQ ID NO: 7594, SEQ ID NO: 7596, SEQ ID NO: 7602, SEQ ID NO: 7612, SEQ ID NO: 7617, SEQ ID NO: 7618, SEQ ID NO: 7622, SEQ ID NO: 7624, SEQ ID NO: 7627, SEQ ID NO: 7631, SEQ ID NO: 7632, SEQ ID NO: 7644, SEQ ID NO: 7646, SEQ ID NO: 7655, SEQ ID NO: 7657, SEQ ID NO: 7659, SEQ ID NO: 7677, SEQ ID NO: 7682, SEQ ID NO: 7685, SEQ ID NO: 7690, SEQ ID NO: 7694, SEQ ID NO: 7697, SEQ ID NO: 7701, SEQ ID NO: 7702, SEQ ID NO: 7703, SEQ ID NO: 7707, SEQ ID NO: 7708, SEQ ID NO: 7711, SEQ ID NO: 7715, SEQ ID NO: 7718, SEQ ID NO: 7721, SEQ ID NO: 7723, SEQ ID NO: 7724, SEQ ID NO: 7729, SEQ

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NO: 8512, SEQ ID NO: 8517, SEQ ID NO: 8518, SEQ ID NO: 8529, SEQ ID NO: 8530, SEQ ID NO: 8538, SEQ ID NO: 8542, SEQ ID NO: 8553, SEQ ID NO: 8554, SEQ ID NO: 8556, SEQ ID NO: 8560, SEQ ID NO: 8568, SEQ ID NO: 8569, SEQ ID NO: 8578, SEQ ID NO: 8579, SEQ ID NO: 8580, SEQ ID NO: 8583, SEQ ID NO: 8584, SEQ ID NO: 8585, SEQ ID NO: 8587, SEQ ID NO: 8590, SEQ ID NO: 8601, SEQ ID NO: 8607, SEQ ID NO: 8611, SEQ ID NO: 8616, SEQ ID NO: 8624, SEQ ID NO: 8625, SEQ ID NO: 8631, SEQ ID NO: 8632, SEQ ID NO: 8639, SEQ ID NO: 8644, and SEQ ID NO: 8665.

The Examiner does not rely on prior art to support the rejections of record.

The rejections as presented by the Examiner are as follows:

1. Claims 8-10 and 12-27 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.
2. Claims 8-10 and 12-27 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

We affirm the rejections under 35 U.S.C. § 101 and under the enablement provision of 35 U.S.C. § 112, first paragraph. We reverse the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

CLAIM INTERPRETATION

Claim 14 is drawn to a microarray. The claimed microarray comprises a substrate with a surface comprising at least 1000 nucleic acid molecules. Claim 14 requires that of these at least 1000 nucleic acid molecules at least 10% of the nucleic acid molecules are:

1. comprised of different sequences;
2. at least about 250 nucleotide residues¹; and
3. complementary² to a molecule comprising a sequence selected from the group consisting of the recited SEQ ID NOs.

As to the SEQ ID NOs. set forth in claim 14, we note that Appellants' Specification discloses that "SEQ ID NO: 5746 through SEQ ID NO: 8666 are from [the] LIB189" cDNA library (Spec. 92: 13-14; Decision 6-7). As Appellants' Specification explains, the LIB189 cDNA library was prepared from leaf tissue harvested at anthesis from field grown *Zea mays* genotype RX601 plants that were "open pollinated plants in a field (multiple row) setting" (Spec. 92: 8-13; Decision 7).

¹ Appellants' Specification discloses that

Agents of the present invention include nucleic acid molecules and more specifically EST nucleic acid molecules or nucleic acid fragment molecules thereof. Fragment EST nucleic acid molecules may encode significant portion(s) of, or indeed most of, the EST nucleic acid molecule. Alternatively, the fragments may comprise smaller oligonucleotides (having from about 15 to about 250 nucleotide residues, and more preferably, about 15 to about 30 nucleotide residues).

(Spec. 16: 20-25; Decision 6: n. 3.)

² According to Appellants' Specification, "the molecules are said to be 'complementary' if they can hybridize to one another with sufficient stability to permit them to remain annealed to one another under conventional 'high-stringency' conditions" (Spec. 18: 11-13; Decision 6: n. 4).

DISCUSSION

Utility:

Claims 8-10 and 12-27 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.³ The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 14.

Initially, we recognize Appellants' assertion that "they have disclosed microarrays and substrates comprising nucleic acid molecules expressed during anthesis in maize plants" (Supp. App. Br. 5). According to Appellants "the microarrays of the present invention can be used for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression so such genes" (Supp. App. Br. 6).

We note, however, that:

the claimed microarrays contain nucleic acid molecules (ESTs) isolated from the LIB189 cDNA library, which was prepared from leaf tissue harvested at anthesis from field grown Zea mays genotype RX601 plants. There is no evidence on this record that LIB189 is a subtractive cDNA library, wherein nucleic acid molecules from maize tissue other than leaf tissue, from developmental stages other than anthesis, and/or from Zea

³ The Examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility (*see* Ans. 5). Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

mays plants other than genotype RX601 is subtracted (removed) from the library.

(Decision 7.)

Therefore, as we understand claim 14, the nucleic acid molecules associated with the claimed microarray represent randomly selected nucleic acid molecules isolated from pooled leaf tissue isolated from *Zea mays* genotype RX601 at the time of anthesis. There is, however, no evidence on this record that any of these randomly selected nucleic acid molecules are expressed only at the time of anthesis, only in leaf tissue, or only in a *Zea mays* plant having the RX601 genotype (Cf. Decision 7-8; *see also* Ans. 6).

In this regard, we note that there are any number of “house-keeping” genes, such as RNA polymerase, that would be expected to be expressed at anthesis and at other times during the plant’s life cycle.⁴ Accordingly, we are not persuaded by Appellants’ unsupported assertion that “the claimed microarrays contain nucleic acid sequences from maize corresponding to genes expressed during anthesis” (Supp. App. Br. 7).

While Appellants identify a number of SEQ ID NOs for nucleic acid molecules expressed during anthesis, Appellants fail to identify any other characteristic of these nucleic acid molecules. Accordingly, it is unclear from Appellants’ disclosure whether any of the EST sequences recited in

⁴ We are not persuaded by Appellants’ assertion that “not every nucleic acid is expressed during anthesis” and that “all nucleic acids are not expressed at some point” (Supp. App. Br. 8 (emphasis removed)). While true, the argument misses the point. Appellants appear to ignore the fact that some nucleic acids are expressed both during anthesis and at other stages of a plant’s life cycle. A representative example is RNA polymerase, without which no gene expression would be observed at *any* stage of a plant’s life cycle.

Appellants' claim 14 are expressed only during anthesis or instead are, like RNA polymerase, expressed during a variety of different stages in a plant's life cycle. Therefore, we disagree with Appellants' assertion that simply "because the nucleic acids of the claimed microarray were expressed during anthesis, which is a 'particular phenotype, condition or state' . . . the nucleic acids 'have an immediate applicable utility'" (Supp. App. Br. 8). Stated differently, simply because a particular EST is present during anthesis does not mean that a microarray comprising this EST has utility in identifying plants in anthesis.

We are also not persuaded by Appellants' assertion that "the Examiner's arguments that the patentability of the claims is based on the utility of individual nucleic acid sequences alone is improper" (Supp. App. Br. 9). The utility of a microarray depends on the reagent, in this case the nucleic acid molecules, associated with the microarray (Decision 10). Thus the issue before this panel is not whether microarrays are generally useful; to the contrary, the question is whether Appellants have satisfied the utility requirement for a very specific microarray that comprises at least 1000 nucleic acid molecules, where at least 10% of these nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and are complementary to particular ESTs identified by SEQ ID NO., as set forth in Appellants' claim 14 (*Cf.* Decision 10). Where, as here, the nucleic acid molecules associated with the microarray have no utility, the microarray also has no utility. For the same reasons, we are not persuaded by Appellants' assertion that a person of ordinary skill in the art could modify Appellants' claimed microarray to produce a useful device (Supp. App. Br. 10).

For the reasons set forth on pages 11-17 of the Decision, we are not persuaded by Appellants' assertion that their "specification discloses specific and substantial uses for the claimed microarrays, including use to analyze biological samples for the presence of maize nucleic acid sequence homologues . . . and in high-throughput monitoring of gene expression in a corn plant" (Supp. App. Br. 11).

The U.S. Court of Appeals for the Federal Circuit has held that § 101 requires a utility that is both substantial and specific. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). The court held that a substantial utility requires showing that "an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Id.*

The court held that a specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

The court held that the uses asserted in *Fisher* were not substantial or specific because

the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. . . . Accordingly, the claimed ESTs are, in words of the Supreme Court, mere "object[s] of use-testing," to wit, objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end.

Id. at 1373 (alteration in original). The court concluded that “Fisher’s asserted uses are insufficient to meet the standard for a ‘substantial’ utility under § 101” (*id.*).

Furthermore, Fisher’s seven asserted uses are plainly not “specific.” Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher’s seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the ‘643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

Id. at 1374.

Here, the utility of the claimed microarray depends on the utility of the nucleic acids recited by SEQ ID NO. in claim 14. Therefore, as discussed above, if the disclosed nucleic acids lack utility, so does the claimed microarray, which comprises these sequences.

In sum, as to the utility of the nucleic acid molecules themselves, we find *Fisher* to be controlling. This case differs from *Fisher* in that Appellants have placed the uncharacterized nucleic acid molecules (ESTs) on a microarray. However, for the foregoing reasons, we find that Appellants have not satisfied the utility requirement for a claim drawn to a microarray as set forth in claim 14 that comprises a number of nucleic acids, which but for their sequence, remain uncharacterized.

Accordingly, we affirm the rejection of claim 14 under 35 U.S.C. § 101, and the enablement provision of 35 U.S.C. § 112, first paragraph. As they are not separately argued, claims 8-10, 12, 13, and 15-27 fall together with claim 14.

Written Description:

Claims 8-10 and 12-27 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

The rejection is based on the Examiner's concern that Appellants' use of the transitional term "comprising" results in claims drawn to a large genus of nucleic acid molecules which are not adequately described by the recitation of the sequence by SEQ ID NO. (Ans. 10). We disagree.

As Appellants explain, they "have fully described each SEQ ID NO by setting forth its nucleotide sequence" (Supp. App. Br. 15). According to Appellants, they "have provided the nucleotide sequences recited by the claims . . . and have disclosed microarrays comprising such sequences, and have thus established possession of the claimed invention" (Supp. App. Br. 16). We agree.

The use of the transitional term "comprising" does not allow for internal alterations (e.g. insertions or deletions) of the nucleotide sequences set forth in Appellants' claims, but instead only allows for the addition of nucleotides or other molecules at either end of the nucleotide sequences. Accordingly, we agree with Appellants that they have provided an adequate written description of nucleic acid molecules with the sequences set forth in their claims. That these nucleic acid molecules may have other molecules attached to either, or both of their 5' or 3' ends does not diminish Appellants' adequate written description of the nucleic acids molecules with the sequences set forth in their claims.

Accordingly, we reverse the rejection of 8-10 and 12-27 under the written description provision of 35 U.S.C. § 112, first paragraph.

CONCLUSION

In summary, we affirm the rejections under 35 U.S.C. § 101 and under the enablement provision of 35 U.S.C. § 112, first paragraph. We reverse the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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